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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,098	05/15/2000	ALFREDO NICOSIA	MEWBURN	5857

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PHILADELPHIA, PA 19103-2307

EXAMINER

BHATTI, TAHIRA H

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 05/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/463,098

Applicant(s)

NICOSIA ET AL.

Examiner

Tahira H Bhatti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 32-57 is/are pending in the application.
- 4a) Of the above claim(s) 46-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 32-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. Claims 32-57 are currently pending.
2. Claims 7-9, 11, 14, 17, 19, 22, 24, 31, 32, 35, 39, 42, 46, 49, 50—52, 55, 58, 60, 62, 64, 65, 68, 70-78, 81, 82, 84-86, 88-93 and 95-96, were amended by the applicant's preliminary amendment (A), dated 5/15/00 in paper NO: 5 is acknowledged.
3. The preliminary amendment (A), cancelled claims 15, 16, 18, 59, 63, 69, 79, 80, and 87.
4. Claims 1, 4, 31, 32, and 47-49, were amended by the applicant's preliminary amendment (C), dated 1/8/02, in paper NO: 16 is acknowledged.
5. Applicants election of Group II (Claims 32-57) in response to restriction requirements in paper NO: 13, dated 7/9/01 is acknowledged.
6. Applicant further election of Formula II or in composition form is acknowledged.
7. Claim 46-57 and subject matter not drawn to Formula II is withdrawn from consideration on being drawn to non-elected species.
8. Claims 32-45 are currently being examined.

Sequence rule compliance

9. Applicant is not in complete compliance with the requirements for the sequence rules as set forth in 37 C.F.R. 1.821-1.825. "SEQ ID NO"(s), should refer to each sequence in the description, claims or drawings of the application. Specification and

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claims (i.e. claims 35-38) are objected to for lack of compliance with sequence rules:
see 37 CFR 1.821 (d) requiring sequence identifiers.

OBJECTION

10. Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 33 provides "a composition including a plurality of peptides" which is further broader than claim 32.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claim 32-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following enumerated reasons apply.

12. Claim 32 is rejected because it recites " library according to claim 1". It is indefinite and confusing since claim 1 is cancelled.

13. Claims 33-34 and 45 recite "obtainable". It is indefinite and vague, without specifying what is obtainable.

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14. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language "figure 7 (A)". Additionally the subject matter in the "figure 7 (A)", must be incorporated in this claim, see MPEP 2173.05.

15. Claim 35-38 contains the trademark/trade name G31, F78, R9, D6, M122 and H1. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe peptides and, accordingly, the identification/description is indefinite.

16. Claims 39, 40, 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

17. The present claims are directed to a composition where the plurality of peptides is in fusion proteins with additional amino acid. It is noted that there is no claimed structure or other identifying characteristics presented with respect to the final composition. It

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corresponds to any additional peptides, which are not defined or specified with regard to their function, property, structure or other identifying characteristics presented with respect to their chemical reactions.

18. The specification description is directed to a composition which clearly does not provide an adequate representation regarding the composition and the additional amino acid made by the presently claimed invention.

19. With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

20. Although directed to DNA compounds, this holding would be deemed to be applicable to any compound; which requires a representative sample of compounds and/or a showing of sufficient identifying characteristics; to demonstrate possession of the claimed generic(s).

21. In the present instance, the fusion protein and the additional amino acids fail to further limit the claimed invention, representing no identifying characteristics.

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Additionally, the broad scope of the claim directed to fusion protein with plurality of peptides and with additional amino acids, are clearly not representative of the scope of the presently claimed invention.

22. In this regard, applicant is referred to the seminal case of *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and the resulting "Guidelines for Examination of Patent Applications Under the 35 USC 112, first paragraph, 'Written Description' Requirement" published in 1242 OG 168-178 (January 30, 2001).

23. It is first noted that written description is legally distinct from enablement: "Although the two concepts of are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures the that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention." See 1242 OG 169 (January 30, 2001) citing *University of California v. Eli Lilly & Co*

24. With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in

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University of California v. Eli Lilly defined the invention by function of the claimed DNA (encoding insulin)].

25. As pointed out in the above rejection, the specification does not disclose adequately the fusion protein nor it explains the additional amino acids. Only limited examples are presented, that are neither representative of the fusion and neither do they represent additional amino acids. The specification description examples are directed to peptides with out specifying them. This showing clearly does not provide an adequate representation regarding the composition.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

26. Claims 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

27. Claims 39-41 recite " peptide in a fusion with additional amino acids ". This is vague and indefinite. It is not clear what is meant by " in a fusion and further "additional amino acid" residues should be specified.

28. Claim 42, recites "at least one additional component". It is not clear what the additional component is.

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General information regarding further correspondence

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Tahira Bhatti whose telephone number is (703) 605-1203. The examiner can normally be reached between Monday to Friday from 8:00 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothisana Venkat (art unit 1627), can be reached at (703) 308 0570. Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (702) 308-1234

Tahira Bhatti (art unit 1627)

April 30, 2002

BENNETT CELSA
PRIMARY EXAMINER


